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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,301	07/17/2006	Jacqueline Dalby-Payne	FBR0002US.NP	2194

26259 7590 03/27/2007  
LICATA & TYRRELL P.C.  
66 E. MAIN STREET  
MARLTON, NJ 08053

EXAMINER
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LEE, JAE W

ART UNIT	PAPER NUMBER
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1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/27/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/549,301

Applicant(s)

DALBY-PAYNE ET AL.

Examiner

Jae W. Lee

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 44-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 44-77 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____                                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____   | 6) <input type="checkbox"/> Other: ____                           |

## **DETAILED ACTION**

### ***Application status***

Claims 44-77 are pending in the instant application.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 44-62, drawn to a method of screening for a compound that regulates an activity of a cell surface protein, the method comprising analysing an activity or cellular location of tropomyosin, expression levels of tropomyosin, or binding of tropomyosin to one of its binding partners in the presence of a candidate compound, wherein altered tropomyosin activity or cellular location, altered expression levels of tropomyosin or an altered level of binding of tropomyosin to its binding partner in the presence of the compound indicates that the compound regulates the activity of a cell surface protein, and a method of screening for a therapeutic compound for treatment of cystic fibrosis, the method comprising analysing an activity or cellular location of tropomyosin, expression levels of tropomyosin or binding of tropomyosin to one of its binding partners in the presence of a candidate compound, wherein altered tropomyosin activity or cellular location, altered expression levels of tropomyosin or an altered level of binding of tropomyosin to its binding partner in the presence of the compound indicates that the compound is useful for treatment of cystic fibrosis.

Group II, claim(s) 63-77, drawn to a method for regulating insertion or retention of a protein in a cell surface membrane, the method comprising administering to a cell an agent that modulates tropomyosin expression, location or activity, and a method for the treatment or prevention of cystic fibrosis in a subject, the method comprising administering to a subject an agent that modulates tropomyosin expression, location or activity.

In addition to the above election, the claims are subject to further restriction requirement. Please elect one of (A)-(D):

(A) SEQ ID NO: 11 encoded by SEQ ID NO: 7 drawn to TPM 1

(B) SEQ ID NO: 12 encoded by SEQ ID NO: 8 drawn to TPM 3

(C) TMP5a

(D) TMP5b

The TMP1, 3, 5a and 5b are independent or distinct because they represent structurally different proteins (amino acid sequences), and where structural identity is required, such as for hybridization or expression, the different sequences have different effects. Therefore, they lack unity of invention under PCT Rule 13.2.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Davis et al. (*In vitro* activation of the interferon-induced, double-stranded RNA-dependent protein kinase PKR by RNA from the 3' untranslated regions of human

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alpha-tropomyosin, PNAS, 1996, 93: 508-513) teach a method of analyzing expression levels of tropomyosin containing 3'UTR by isolating and cloning said tropomyosin RNA sequences, wherein translation of said sequences (see pg. 509, left column) results in activation of PKR kinase activity, which in turn alters morphological and growth pattern alters in NIH3T3 cells by acting as a tumor suppressor (see pg. 508, right column), thereby regulating the activity of a cell surface protein, which corresponds to the limitation of claim 1, in the recitation of "a method of screening for a compound that regulates an activity of a cell surface protein, the method comprising analysing an activity or cellular location of tropomyosin, expression levels of tropomyosin, or binding of tropomyosin to one of its binding partners in the presence of a candidate compound, wherein altered tropomyosin activity or cellular location, altered expression levels of tropomyosin or an altered level of binding of tropomyosin to its binding partner in the presence of the compound indicates that the compound regulates the activity of a cell surface protein," and thus, the shared technical feature of the groups is not a "special technical feature", unity of invention between the groups does not exist.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Because these inventions are unrelated and distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Group is not required for

another thereby presenting a search burden on the Examiner, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

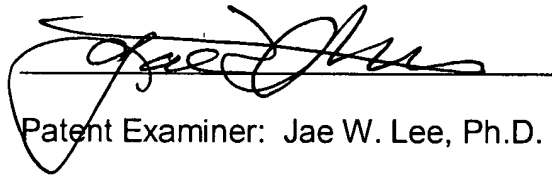
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen K. Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

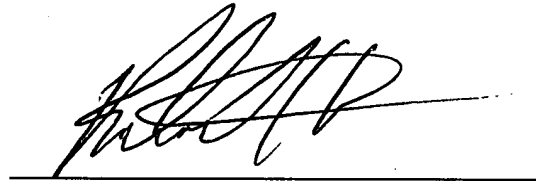
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Patent Examiner: Jae W. Lee, Ph.D.



**RICHARD HUTSON, PH.D.**  
**PRIMARY EXAMINER**